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PATENT & TRADEMARK OFFICE

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BSI-030US7 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Continuation Application from	:
U.S. Serial No. 09/687,247	: Attention:
Applicant: Andrew H. Cragg	: Box Missing Parts
Serial No.: 10/087,320	:
Filed: March 1, 2002	: Art Unit 3731
FOR: INTRALUMINAL STENT AND GRAFT	: Examiner

20/17/02 02 3/800 1

SUBSTITUTE PREIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

SIR:

Prior to examination, please disregard the Preliminary Amendment filed on March 1, 2002 and substitute this Preliminary Amendment, the page and line numbers of which correspond to those of the Substitute Specification filed herewith. More specifically, please amend the Substitute Specification in the above-identified application as follows:

IN THE SUBSTITUTE SPECIFICATION:

Please amend the specification on Page 1, following the title, by deleting the first full paragraph and replacing it with the paragraph as follows:

This is a continuation application of U.S. Application No. 09/687,247, filed October 13, 2000, which is a continuation of U.S. Application No. 09/251,964, filed February 16, 1999, which is a continuation of U.S. Application No. 09/005,654, filed January 12, 1998, which is a continuation of U.S. Application Serial No. 08/478,181, filed June 7, 1995, which is a division of U.S. Application No. 08/344,524, filed November 23, 1994, which in turn is a continuation of U.S. Application No.

08/025,957, filed March 3, 1993, which in turn is a continuation-in-part of U.S. Application No. 07/839,911, filed February 21, 1992.

Please replace the paragraph, beginning at Page 6, line 1, with the following:

Turning now to FIGS. 7-9, an alternative embodiment of the present invention includes the wire body and suture connections described above. This alternative also includes a prosthetic graft 13 disposed inside the central opening of the wire body. The graft is a round, open tube made of polytetrafluoroethylene (PTFF), dacron or any other suitable biocompatible material. One or more loop members 12 connect the graft 13 to the wire body 11 as shown in FIG. 9. In place, the graft closes the diamond shaped openings of the stent structure to further minimize plaque herniation and minimize the flow of fluid and cellular elements through the structure.

Please replace the paragraph beginning at Page 6, line 19, with the following:

In one example, the graft 13 is a plain weave fabric construction made in a seamless tubular form on conventional equipment, either a shuttle narrow fabric weaving machine or a needle narrow fabric weaving machine. The tube is of multi filament polyester yarn of 40 denier or less (preferably 20, 30 or 40 denier). The wall thickness of the tube is 0.2 mm or less (preferably 0.1 mm); and it has a water permeability of between 50 and 500 ml/cm^2/min at 16 kPa (millimeters of water per square centimeter per minute at a pressure of 16 kPa). The fabric may be coated with a drug substance to reduce permeability, cause local anticoagulation, or reduce cellular infiltration.

IN THE CLAIMS:

Please cancel claims 1-9 and add the following new claims 10-28.

10. (Newly Added) A stent-graft combination comprising a tubular stent having a plurality of hoops aligned adjacent one another along

the axis of said hoop stent, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, further including a tubular graft member disposed circumferentially adjacent the tubular stent.

11. (Newly Added) A stent-graft combination according to claim 10, wherein said stent is comprised of a shape memory material.

12. (Newly Added) A stent-graft combination according to claim 10, wherein said shape memory material is nitinol.

13. (Newly Added) A stent-graft combination according to claim 10, wherein said stent is comprised of an elastic material.

14. (Newly Added) A stent-graft combination according to claim 10, wherein said elastic material is stainless steel.

15. (Newly Added) A stent-graft combination according to claim 10, wherein said graft covers diamond shaped openings in said stent.

16. (Newly Added) A stent-graft combination according to claim 10 wherein said graft covers diamond shaped openings in said stent and is attached to said stent by ligature loops.

17. (Newly Added) A stent-graft combination according to claim 16, wherein said ligature loops also form connections between abutting apices of said stent.

18. (Newly Added) A stent-graft combination according to claim 10, wherein the graft is disposed on the outer surface of the stent.

19. (Newly Added) A stent-graft combination according to claim 10, wherein the graft is disposed on the inner surface of the stent.

20. (Newly Added) A stent according to claim 10, wherein said graft member including a drug substance disposed thereon.

21. (Newly Added) A stent according to claim 10, wherein said graft comprises polyester or polytetrafluoroethylene.

22. (Newly Added) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing stent-graft combination as recited in claim 10;

b. compressing the stent-graft combination into its compressed configuration;

c. inserting the compressed stent-graft combination into the tubular sheath;

d. delivering the compressed stent-graft combination through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent-graft combination within the implantation location as the sheath is withdrawn by permitting the self-expandable stent-graft combination, as the constraint of the sheath is removed, to return to said expanded configuration;

whereby the stent-graft combination is securely disposed in the implanted state against said body vessel.

23. (Newly Added) A method according to claim 22, wherein the stent of said stent-graft combination is comprised of a shape memory material.

24. (Newly Added) A method according to claim 23, wherein said shape memory material is nitinol.

25. (Newly Added) A method according to claim 22, wherein the stent of said stent-graft combination is comprised of an elastic material.

26. (Newly Added) A method according to claim 25, wherein said elastic material is stainless steel.

27. (Newly Added) A method according to claim 24, wherein step b is performed at a reduced temperature such that the nitinol is not elastic.

28. (Newly Added) Method of implanting a prosthesis at an implementation site in a body lumen comprising providing a stent graft combination as recited in claim 10, said stent-graft combination having first and second configurations the diameter of said stent or prosthesis in said first configuration being smaller than in said second configuration, said method comprising introducing said stent or prosthesis, while in its first configuration into a body lumen in communication with said implantation site but remote therefrom, transporting said stent-graft combination to said implantation site and causing or permitting said stent-graft combination to assume its second configuration, whereby it is retained at said implantation site.

REMARKS

The office has required a Substitute Specification for this application, which is filed herewith. The purpose of this Substitute Preliminary Amendment is to make the same changes, with reference to the page and line numbers of the Substitute Specification, as had originally been made in the original specification.

Entry of the above claims prior to examination is respectfully requested.

Respectfully submitted,

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Dated: April 9, 2002

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The Assistant Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on:

4/9/02

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Specification at page 1, line 1:

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Specification at page 6, line 9:

Turning now to FIGS. 7-9, an alternative embodiment of the present invention includes the wire body and suture connections described above. This alternative also includes a prosthetic graft 13 disposed inside the central opening of the wire body. The graft is a round, open tube made of polytetrafluoroethylene (PTFF), dacron or any other suitable bicompatible material. One or more ~~hoop~~ loop members 12 connect the graft 13 to the wire body 11 as shown in FIG. 9. In place, the graft closes the diamond

shaped openings of the stent structure to further minimize plaque herniation and minimize the flow of fluid and cellular elements through the structure

Specification at page 6, line 19:

In one example, the graft 13 is a plain weave fabric construction made in a seamless tubular form on conventional equipment, either a shuttle narrow fabric weaving machine or a needle narrow fabric weaving machine. The tube is of multi filament polyester yarn of 40 denier or less (preferably 20, 30 or 40 denier). The wall thickness of the tube is 0.2 mm or less (preferably 0.1 mm); and it has a water permeability of between 50 and 500 ml/cm^2/min at 16 kPa (millimeters of water per square centimeter per minute at a pressure of 16 kPa). The fabric may be coated with a drug substance to reduce permeability, cause local anticoagulation, or reduce cellular ~~infaltration~~ infiltration.

IN THE CLAIMS:

Claims 1-9 have been cancelled.

Claim 10-28 have been added.